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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,836	08/03/2001	Andrew Bett	20377YP	7869
210	7590	11/01/2005	EXAMINER	
MERCK AND CO., INC			HILL, MYRONG	
P O BOX 2000			ART UNIT	PAPER NUMBER
RAHWAY, NJ 07065-0907			1648	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,836

Applicant(s)

BETT ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to amendment filed 27 December 2004.

Claims 1-15 are under consideration.

Claim Objections Withdrawn

Claims 10- 15 re objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims 10-13 depend on a claim that is a nucleic acid.

The claims have been amended and the rejection is withdrawn.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 7, and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardy (WO97/32481) in light of Grable *et al.* (1990, IDS).

The claims have been amended and the rejection is withdrawn.

Rejections Necessitated By Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the packaging signal can comprise zero elements and it is not clear how the A elements can be different if there is only one A element.

Claim Rejections - 35 USC § 103

Claims 42, 43, 45-7, and 50-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy (WO97/32481) in light of Grable *et al.* (1990, IDS) and Schmid *et al.* (J Virol 1997, from IDS).

The limitation of "where N8 of each element is replaced by the N8 of a different A element" is interpreted as each N8 is different. The claim recites "comprising" and can include more than just A elements and does not require that the elements be in any specific order or not in wild type order.

Hardy is discussed in the previous action and teaches synthetic packaging sequences with 6 A elements and recombinase recognition sites in a packaging vector.

Hardy does not teach repeats, each repeat having the consensus sequence (SEQ ID#1) and each N8 is replaced by the N8 of a different element.

Grable *et al.* teach a synthetic packaging signal that includes only one consensus A element (Figure 3, construct di309-261/358 or Figure 7 sixth from top) and two A elements (Figure 7 third from top).

Schmid *et al.* is a further study of the packaging signals taught by Grable *et al.* and Schmid *et al.* teach the A repeat of SEQ ID# 1 (Figure 4). As well as they teach a construct that contains two consensus sequences (SEQ ID #1) with different N8 sequences (Figure 2 B, construct IN 258/259). Schmid *et al.* also teach that there are 21 nucleotides between repeats I and II and between repeats V and VI.

One of ordinary skill in the art at the time of invention would have been motivated to use the corrected A repeat sequence of Schmid *et al.* in the low homology packaging cassette of Hardy because this was shown to be the consensus sequence of the packing motif. One of ordinary skill in the art at the time of invention would have known 21 nucleotides is a preferred distance between A repeats.

One of ordinary skill in the art at the time of invention would have known that Grable *et al.* and Schmid *et al.* teach a range of synthetic packaging signals and that they provide reduction of yield information to show that these synthetic packaging signals package less efficiently as required by Hardy. One of ordinary skill in the art at the time of invention would have been motivated to use the two A elements of Schmid *et al.* Figure 2 B because it is shown to be synthetic and package less efficiently.

Thus, it would have been *prima facie* obvious to modify the packaging signal of Hardy with the correct sequence of A repeat and synthetic packaging signal of Schmid *et al.* with the expectation of success because the synthetic packaging signal of Schmid *et al.* is shown to have the properties required by Hardy.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1648

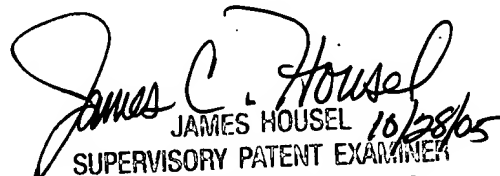
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner
24 October 2005



JAMES HOUSEL 10/28/05
SUPERVISORY PATENT EXAMINER
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